IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

ALMA DUSEK, INDIVIDUALLY	§	
AND AS ADMINISTRATRIX OF	§	
THE ESTATE OF CYRIL DUSEK,	§	
DECEASED, RON DUSEK	§	
AND PEGGY KUSY,	§	
Plaintiffs,	§	
	§	
v.	§	C. A. NO. H-02-3559
	§	
PFIZER, INC. AND	§	
CHAS. PFIZER & CO., INC.	§	
N/K/A PFIZER, INC.,	§	
Defendants.	§	

AFFIDAVIT OF JESSICA R. DART

1. My name is Jessica Rae Dart and I am over the age of 21 years, of sound mind, and am fully competent to make this affidavit. The facts contained herein are within my personal knowledge and are true and correct. This Affidavit is being prepared to file in support of Plaintiffs' Motion for Reconsideration and Alternative Motion for Clarification of the Opinion and Order dated February 20, 2004. In addition to being Plaintiffs' Counsel in this case, I am also one of Plaintiffs' Counsel in both *Motus v. Pfizer, Inc.* 127 F.Supp.2d 1085, 1095 (C.D.Cal.,2000), and *In Re Paxil,* CV-01-07937 MRP.

2. On December 15, 2003, Mr. Daniel E. Troy, Chief Counsel of the FDA, headed a discussion for pharmaceutical firms and defense lawyers entitled: "The Case for Preemption" at the "8th Annual Conference for In house Counsel and Trial Attorneys, Drug and Medical Device Litigation" in New York City. (*See* Conference Advertisement, a true and correct copy of which is attached as Exhibit 7.)

3. The advertised and actual content of Mr. Troy's talk included a discussion about the FDA's involvement in *In Re Paxil* and *Motus v. Pfizer*. As there were no restrictions on admission, I attended the conference, spoke with Mr. Troy after his talk, and personally witnessed Mr. Troy making numerous statements which directly undermine the credibility of the position attributed to the FDA in both of the above referenced cases.

4. The following statements are based on the detailed notes I took during the conference. These notes were taken for the purpose of writing Declarations to submit in *Motus v. Pfizer* and *In Re Paxil*. While I have yet to file these Declarations in either case, the following text is mostly excerpted from those Declarations.[1]

5. During Mr. Troy's "Case for Preemption" talk, Mr. Troy stated that *he* was the initiator behind all of the FDA Amicus Briefs and/or Statements of Interest filed on behalf of manufacturers "since the new administration" took over. Specifically, he stated: "I am not the only one who decides," but "I am the initial proposer." With respect to *In Re Paxil* in particular, Mr. Troy stated: "what prompted me to get involved in *In Re Paxil*, was that I heard that the judge said that something could be misleading under state law, but not misleading to the FDA. That's Crazy. I just had to get involved then." Mr. Troy also made it clear that he was interested in filing even more amicus briefs on behalf of pharmaceutical manufacturers and actually invited his defense counsel audience to approach him with requests for amicus briefs, stating: "we can't afford to get involved in every case," we have to "pick our shots," so "make it sound like a Hollywood pitch."

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[1] To the extent that I quote Mr. Troy, I believe these quotes to be 100% accurate, having written down his exact words. Nonetheless, because I did not write down everything Mr. Troy said, and because I may have made some errors, this Declaration is being offered only as my immediately recorded impression of Mr. Troy's statements and speech.

6. While Mr. Troy has characterized the FDA's new practice of intervening in private lawsuits as what is necessary to protect the FDA's territory, conference attendees did not have to strain to discern that tort reform was Mr. Troy's true agenda. From the very first words of his speech, to the end of the roundtable discussion, Mr. Troy made it abundantly clear that the FDA would exercise its intervention powers to protect defendants from liability in state and federal courts throughout the nation.[2] Specifically, Mr. Troy stated that "the McClellan administration is deeply immersed in tort reform issues," and that it was the FDA's goal to "control the flow of risk info regarding these [drug and medical devise] products."

7. Mr. Troy also stated that: "minimizing product liability is not part of the FDA's mandate, but we are aware that our decisions do effect liability and we think it's consistent to step into litigation and still fulfil our mandate." This statement, in-and-of- itself would not be that remarkable, if Mr. Troy had stopped there. Instead, however, Mr. Troy went on to reveal that the FDA in fact had "no good evidence" demonstrating that product liability concerns "keep good products off the market" and the he had "combed the literature" to find such evidence, but had come up empty. He then said that he hoped the conference attendees would attempt to find such evidence for him, stating: "you guys really shoot yourself in the foot by not funding research to this effect. . . . I'll even take anecdotal evidence and stories if you have them."

8. In direct conflict with Mr. Troy's duty to avoid the appearance of impartiality as an executive branch official,[3] Mr. Troy made numerous derogatory remarks about plaintiffs, "runaway juries,"

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[2] Mr. Troy opened his speech with a joke about a man who called his lawyer, only to find out that his lawyer had died the day before. Each day, however, the man continued to call and ask for his lawyer. After the third day, the receptionist grew tired of the man's requests to speak to his lawyer and said: "Mr. Smith, how many times do I have to tell you, you're lawyer is dead." Mr. Smith responded: "I know he's dead, but I just love hearing that." **Mr. Troy concluded the joke by saying, "I'd like to believe that Mr. Smith was a plaintiff."**

[3] *See e.g.* 5 C.F.R. § 2635.501 (*stating*: "An employee who is concerned that other circumstances would raise a question regarding his impartiality should use the process described in § 2635.502 to determine whether he should or should not participate in a particular matter."); *see also* 1990 WL 385168 (Pres.) ("Executive Order 12731") ("(g) Employees shall not use public office for private gain.(h) Employees shall act impartially and not give preferential treatment to any private organization or individual. . . ."(n) Employees shall endeavor to avoid any

and even called the attorneys representing the plaintiffs in *Dowhal v. SmithKline Beecham* (another case in which Troy involved the FDA) "bounty hunters."[4] Mr. Troy also stated that the top three goals of the administration were "innovation, availability and affordability." No mention was made of the FDA's real mandate, which is to *regulate* manufacturers on behalf of consumers to help ensure that dangerous products do not endanger public health.

9. Mr. Troy's willingness to speak at defense orientated symposia[5] to provide suggestions to pharmaceutical companies as to how best to use the preemption defense was only matched by his statement that, (in the cases in which the FDA had recently intervened) he did not think that the plaintiffs should be allowed to take the depositions of FDA officials. Despite the fact that the FDA's briefs have all been filed on behalf of manufacturers, and despite the fact that these briefs are an attempt to deprive each plaintiff of their state law rights (not to mention their right of court access to have their claims heard), Mr. Troy said that allowing plaintiffs to depose FDA witnesses would be a waste of FDA resources and that "the minute the deposition of an FDA official is allowed, I will stop filing amicus briefs."

10. When the roundtable presentation broke up, I approached Mr. Troy and asked him some additional questions concerning his conflict preemption position in the prescription drug context.[6]

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actions creating the appearance that they are violating the law or the ethical standards promulgated pursuant to this order.").

[4] *See Dowhal v. SmithKline Beecham Consumer Healthcare,* 100 Cal.App.4th 8, 122 Cal.Rptr.2d 246 (2002), rev. granted. 10-23-02, No. S109306.

[5] To my knowledge, Mr. Troy has attended at least three other drug conferences where he has discussed similar topics.

[6] My discussion with Mr. Troy mostly centered around his amicus brief involvement on behalf of his former client, Pfizer, in the case of *Motus v. Pfizer, Inc.* 127 F.Supp.2d 1085, (C.D.Cal.,2000). As the Court will recall, Pfizer's National Lead Counsel admitted that he called Mr. Troy and requested the FDA's assistance in the *Motus* case. At the December 15, 2003 conference, Mr. Troy did not deny that Pfizer was a former client (although he did deny having done any work on Mrs. Motus' case while Pfizer was a client). He stated, however, that he had asked his attorney if it was okay for him to get involved in *Motus* and his attorney had told him it was fine. Mr. Troy told

Specifically, I asked him if the FDA was required to do anything formal or final to create a federal requirement that would conflict with a plaintiff's failure to warn claim, or was it enough simply for the FDA to look at the safety issue informally and decide that it would not require a prescription drug warning? In answer, Mr. Troy said: "We think so." He then went on to say: "That's what happened in *In Re Paxil*." Although I cannot remember the *exact* words he used immediately thereafter, to the best of my recollection Mr. Troy said: "What happened in *In Re Paxil* was that the FDA had looked at the advertisement, saw the habit-forming language, told GlaxoSmithKline the exact language to use, and that was it." I then followed up with the question: "And that informal review is enough?" Mr. Troy said: "Yes."

11. When I asked him what his response was to the argument that preemption could not occur until *after* the FDA brought an enforcement action and a determination was made by a court that inclusion of a warning would in fact constitute misbranding (as the misbranding determination is for the court, not the FDA, to make),[7] Mr. Troy (after a long pause) said it would be inefficient to force the FDA to bring enforcement actions every time they wanted to prohibit a warning, but he provided no direct response as to why preemption could legally occur without some kind of formal determination.

12. Mr. Troy's view that informal FDA consideration is all that is required for conflict preemption to exist in the prescription drug context is not supported by the weight of authority. While other speakers at the conference acknowledged that the preemption defense would be a "hard sell" to federal

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me that if we, as Mrs. Motus' Counsel, did not like what he was doing, we could file an ethics complaint.

[7] Under the FDCA, the determination that a drug is misbranded is not the FDA's to make. Instead, if the FDA wants to pursue enforcement action for alleged misbranding, the agency must initiate an action against the manufacturer in a federal district court, and the manufacturer is entitled to a jury trial. 21 U.S.C. § 332 (injunctions), § 333 (criminal penalties), § 334 (seizure). Thus, because the filing of an enforcement action does not guarantee that the FDA will prevail, no conflict would exist until the FDA had won the action. As the Supreme Court has explained: "The existence of a hypothetical or potential conflict is insufficient to warrant the preemption of the state [law]." *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982).

judges because of federalism and well-established precedent rejecting preemption in the prescription drug context, Mr. Troy stated that the FDA's authority was "virtually plenary" and that the FDA has the authority to determine not only "the floor" of prescription drug warnings, but also "the ceiling."

13. Two FDA officials at the February 2, 2004, hearing, Drs. Russell Katz and Robert Temple[8], who were most responsible for reviewing the risks of SSRI drugs and approving SSRI new drug applications ("NDA's") and labeling, both stated, when asked by Plaintiffs' Counsel, that they were unaware that an Amicus Brief had been filed on behalf of the FDA in the *Motus v. Pfizer* case[9]. When pressed, Dr. Temple stated that it would be inappropriate for the FDA to get involved in private litigation and the only FDA brief they were aware of involving SSRI's was the one filed in *In Re Paxil* about GlaxoSmithKlines's "non-habit forming" television commercial. When Plaintiffs' Counsel physically presented the Brief and again asked if the FDA was aware of the specific statements attributed to the FDA in the Brief, Dr. Temple told Plaintiffs' Counsel and a handful of remaining conference attendees and waiting reporters "you'll have to ask the Chief Counsel's office about that." When Dr. Temple was specifically asked "how do you feel about Daniel Troy filing a brief on behalf of the FDA and involving it in private litigation?" Dr. Temple stated, "I would not comment on that in a million years."[10]

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[8] Dr. Russell Katz is the Director of the FDA's Division of Neuropharmacological Drug Products and Dr. Robert Temple is the Director of the Office of Drug Evaluation. These officials are not minor functionaries at the FDA. These are the very men who have the authority for requiring label changes. They are also the very men who appeared at the February 2, 2004, meeting on behalf of the FDA. (See Exhibits 4 and 6, which are true and correct copies of excerpts of the transcript from the February 2, 2004 advisory committee meeting and of organizing charts from the FDA website.)

[9] Specifically, Plaintiffs Counsel asked Dr. Temple and Dr. Katz if they thought that the recommendations of the appointed FDA advisory committee that day ("February 2nd") were inconsistent with the position taken in the FDA's brief that: " "[A]ny warning, no matter how worded, that could reasonably have been read as describing or alluding to such a relation would have been false or misleading, and therefore in conflict with federal law because there was no (and still is not) scientific support for such a warning." *See* FDA Amicus Brief at p. 2. When asked if they were aware of this alleged FDA position, both Temple and Katz said that they were not.

[10] This conversation was witnessed by a number of people and was also recorded by a journalist who has agreed to provide Plaintiffs' Counsel with the recording and a transcript. Plaintiffs' have been unable to get this

14. Attached hereto as Exhibit 1 is a true and correct copy of the stipulation entered by the parties in February 2003.

15. Attached hereto as Exhibit 2 is a true and correct copy of a background memorandum issued by Dr. Thomas Laughren of the FDA for the advisory committee panel members attending the February 2, 2004 advisory committee meeting.

16. Attached hereto as Exhibit 3 is a true and correct copy of a news alert from the website FDAAdvisoryCommittee.com regarding the February 2, 2004 advisory committee recommendations.

17. Attached hereto as Exhibit 5 is a true and correct copy of a letter to health care professionals from Wyeth, the maker of Effexor.

18. Attached hereto as Exhibit 8 is a true and correct copy of an article written by Michael Kranish in the Boston Globe concerning FDA Chief Counsel Daniel Troy.

19. Attached hereto as Exhibit 9 is a true and correct copy of an article that appeared in the San Francisco Chronicle on February 1, 2004 concerning the scheduled February 2, 2004 advisory committee meeting.

20. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 1st day of March, at Los Angeles, California.

LYDIA M. HERNANDEZ
Commission # 1266029
Notary Public - California
Los Angeles County
My Comm. Expires Jun 2, 2004

Jessiea Rae Dart
Counsel for Plaintiffs

Notary

transcript and tape sooner, but should receive them from this journalist this week. Plaintiffs will supplement the record with this recording and transcript as soon as it is received.